

DoD Manufacturing USA Institutes

Monthly Highlights

FORMER FDA OFFICIALS JOIN BIOFABUSA TO HELP DEVELOP ADVANCED MANUFACTURING FOR ENGINEERED TISSUES & ORGANS

BioFabUSA, the DoD Manufacturing USA Institute specializing in advanced tissue biofabrication, welcomed two former officials from the U.S. Food and Drug Administration (FDA). Dr. Richard McFarland and Dr. Becky Robinson-Zeigler recently joined BioFabUSA to provide regulatory science expertise in support of BioFabUSA's efforts towards enhancing the advanced regenerative manufacturing industry.

Regulatory issues are of critical importance to organizations in the field of regenerative medicine, and doctors McFarland and Robinson-Zeigler will support the BioFabUSA program in variety of ways. They will be reviewing technical project proposals with a regulatory science perspective, developing educational and workforce development offerings on regulatory review and processes, and providing individualized consultations with members of BioFabUSA on their product development programs.

Richard McFarland, PhD, MD joined ARMI as its Chief Regulatory Officer in May of this year. Dr. McFarland comes to ARMI from the FDA's Center for Biologics Evaluation and Research (FDA/CBER) where his career of over 16 years involved review of an extensive range of products and policy development in numerous areas inside FDA, across the federal government, and internationally. He spent more than a decade as Associate Director of Policy for



FDA/CBER's Office of Tissues and Advanced Therapies (OTAT), and its predecessor office, the Office of Cellular, Tissue and Gene Therapies (OCTGT).

Robinson-Zeigler, biomedical engineer, recently joined ARMI/BioFabUSA as the Deputy Chief Regulatory Officer. Previously, she was Branch Chief of FDA/CBER/OTAT's Pharmacology/Toxicology Branch (PTB2). In this role, she was responsible for supervising a branch of five pharmacology/toxicology reviewers, and therefore was heavily involved in developing and standardizing review approaches to a wide range of regenerative medicine advanced therapies (RMATs) that were within OTAT's jurisdiction. She also was involved in regenerative medicine initiatives across FDA's Centers, particularly those that spanned CBER and the Center for Device Radiologic Evaluation and (CDRH), including serving as a preceptor in the Commissioner's Regenerative Medicine Fellowship Program, a nonpost-doctoral fellowship designed to train the next generation of regulatory reviewers and scientists.

For more information about BioFabUSA visit https://www.armiusa.org/.

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October 27, 2017 - AFFOA Defense Fabric Discovery Center Grand Opening (Cambridge, MA)

November 1-3, 2017 – ARM Institutes' First Membership Meeting (Pittsburgh, PA)

November 8, 2017 - DMDII Technology Showcase (Chicago, IL)

November 15-16, 2017 - America Makes Members Meeting and Exchange (Youngstown, OH)

<u>December 4-7, 2017</u> – Defense Manufacturing Conference (Tampa, FL)

January 13-15, 2017 – FabLab Innovation Awards and Science Fair (Santa Monica, CA)





DIRECTOR'S CORNER

September 2017 was a especially busy month for our institutes! From hosting member meetings and ribbon cutting events to attending conferences, the DoD Manufacturing USA institutes shared their value adding capabilities with stakeholders in industry, academia, and the public sector. This month's issues highlights NextFlex's Innovation Day, a celebration of the institute's progress on technology projects, workforce development, and much more.

Some other important events in September 2017 include:

- America Makes TRX+ (September 20-21, 2017) America Makes and Autodesk teamed up to deliver TRX Plus (TRX+), an examination of the current landscape of Design for Additive Manufacturing. This intense, two-day event featured America Makes project reports from the America Makes Technology Roadmap along with integrated workshop activities and powerful, insightful presentations from industry experts.
- AIM Photonics Test Packaging and Assembly Tour (September 21, 2017) New York State VIPs toured the progress on the AIM Photonics Testing, Assembly and Packaging (TAP) facility in Rochester. The TAP facility will be used to test, assemble and package chips that use photons in place of electrons for better performing semiconductor circuits.
- LIFT Members Meeting and High Bay Ribbon Cutting (September 27, 2017) LIFT cut the ribbon on their joint facility in celebration of manufacturing and the one-year anniversary of announcing their commitment to bring this facility to Detroit. This \$50 million facility brings together cutting-edge lightweighting applied research and development in metals and composite materials.

-Tracy Frost

Director, DoD Manufacturing USA Institutes Acting Director, DoD ManTech

FOR MORE INFORMATION VISIT:

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STANDING ROOM ONLY CELEBRATION AT NEXTFLEX ANNUAL INNOVATION DAY



On September 21, NextFlex, the Manufacturing USA institute specializing in flexible hybrid electronics (FHE) hosted the Second Annual NextFlex Innovation Day at this facility in San Jose, CA. Designed as a celebration of progress made on project work, ramp-up of the Technology Hub, and results in Workforce Development activities, the event turned out to be much, much more. Over 300 people attended to hear how NextFlex and its members work together to realize the goal of "electronics on everything." Attendees saw firsthand the FHE-enabled technology displays that improve people's daily lives and benefit the safety and security of U.S warfighters. To top it off, NextFlex made the exciting announcement that Qualcomm had joined that day bringing the number of members to 80, almost doubled the number of members since the beginning of the year.



NextFlex Executive Director, Malcolm Thompson, welcomes attendees to the Second Annual NextFlex Innovation Day.

Executive Director Malcolm J. Thompson opened the event by thanking members and government partners, educators, and elected officials in attendance for their generous support over the past year, in helping to achieve the institutes' mission of catalyzing FHE adoption. NextFlex and its members proved that the Institute is a true enabler of innovation as they celebrated 24 member generated projects valued at \$45M (including cost-share) and which represent 212 months of project innovation. Notable speakers included the Honorable Zoe Lofgren, (CA-19) who was instrumental in the passage of RAMI and establishing NextFlex in San Jose; the Honorable Ro Khanna (CA-17); Dr. Jerry McGinn, Acting Deputy Assistant Secretary of Defense, Manufacturing and Industrial Base Policy; COL Charles Ormsby, Acting Director, Materials and Manufacturing Directorate; and Dr. Debbie Budd, Chancellor of EVC/SICC, and our FlexFactor community college partner. Rigid to Flexible Arduino Board

NextFlex demonstrated first-off-the-production-line versions of the flexible Arduino board. Arduino is an open source microcontroller-based system for automation and IOT applications. In its rigid form, the Arduino microcontoller board is widely used for prototyping of new products and has freely available compilers and hardware extension kits, making it a favorite of the maker community and product developers. Redesigning the rigid board to one that is flexible is of interest to the FHE community because of the increasing number of devices that require flexible form factors. NextFlex shared the results of their a complete end-to-end manufacturing process with Innovation Day attendees.

The first-off-the-production-line versions of the flexible Arduino board were demonstrated by NextFlex.

NextFlex offered tours of the NextFlex Technology Hub which houses equipment operated by experienced technical personnel and available as a collaboration center for NextFlex members.

Attendees also enjoyed window tours of the NextFlex Technology Hub. Process capabilities on display included electronic printing and additive processes and curing systems; component integration and assembly; and test and measurement systems. Installed in state-of-the art class 10,000 clean rooms with utilities and environmental controls, all of the equipment is operated by experienced technical personnel and is available as a collaboration center for NextFlex members.

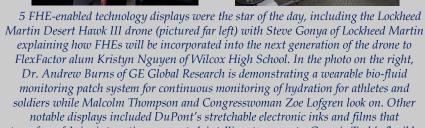
NextFlex also displayed FlexFactor, NextFlex's project-based STEAM learning program for high school students that combines skillbuilding in entrepreneurship, product development, and FHE technology. Twelve FlexFactor alumni shared stories about their experiences and how FlexFactor changed their outlook on manufacturing as a career choice. FlexFactor students are challenged to define a real-world human health problem and develop a business model for an FHE technology solution. At the close of the four-week program, students pitch their product and business plans "shark tank" style to a panel of industry mentors. What started as an idea less than 12 months ago, FlexFactor will reach almost 2,000 Santa Clara County high school students this academic year and considerably more as the program is adopted nationally.

The day before Innovation Day, ten equipment vendors briefed members on the tools installed at NextFlex as part of the Technical Council meeting, and then conducted hands-on demonstrations in the cleanroom with NextFlex staff for nearly 30 members on the day following Innovation Day. A few members expressed interest in spending more time at the facility, and/or contracting with NextFlex for manufacturing or process development work.

Innovation Day was a celebration and affirmation that NextFlex and its members are true enablers of innovation. With this amount of enthusiasm, technical brilliance, and momentum, the next 12 months have a lot in store!

> For more information about NextFlex visit https://www.nextflex.us/.





transform fabrics into active, connected, intelligent garments, Georgia Tech's flexible sensors for wireless human-machine robot interfaces, and many more.















